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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,531	10/30/2003	Frank Worden Hobbs JR.	PH 7069 DIV 1	7567

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/697,531

**Applicant(s)**

HOBBS, FRANK WORDEN

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 09/16/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-7 and 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated Sept. 16, 2004 have been entered and considered carefully.

Claim 8 has been canceled. Claims 11-16 have been newly added.

2. The rejection of claims 8-9 under 35 USC 112 first paragraph for lacking sufficient description and enablement in view of the high degree of unpredictability is maintain for the newly added claims 11-16 for reason of record.

Please note that it was clearly delineated (previous office action, incorporated by reference) that the field of using compounds for treating cancer arthritis etc. through inhibition of MEK1 is highly unpredictable. In the instant case, the amended claims being drawn to R1 being dihydroindol or 5-6 membered heteroaryl lacks sufficient description and enablement since not one compound falls within the newly amended claims 1-16 were disclosed (see specification and CA delineation of structure). In view of the high degree of complexity in the compound claims with such enormous breadth, in absence of any guidance, one skilled in the art are offered mere language rather than enablement.

3. The rejection of claims 1 and 7 under 35 USC (e) over Dent et al. US 6,147,107 which is now applicable to currently amended claims 1-3, 7 is maintained for reason of record.

It is not exactly clear what is the basis of applicant's argument. Is it that the Dent et al. '107 lacks enablement of the compound or the delineation of the compound. The explanation is with respect to if the argument is based on lack of delineation and the CA delineation is not prior art. Please note that the patentability i.e. claim 19 of Dent '107 is not what the structure of the compound is but what is the "product" being used. Please note that it is the "product" not the structural delineation is being patented. The chemical product of US 6,147,107 evidenced by CA 133:34601, is identical to the instant claims, thus, anticipation was found. Many decisions have been set forth by the court that it is the material or product disclosed by the patents that is being used or patented with or without the structural delineation. Ex Parte Deuel 33 USPQ2d 1445. Especially, product without clear understanding of the structure can be patented such as a

Art Unit: 1625

product by process claim. Therefore, the provision of CA 133 evidenced that one skilled in the chemical art will know what the product is and using it by the name SL327 irrespective of the patent itself did not delineate the structure.

4. The rejection of claims 1-10 under the judicially created doctrine of obviousness type double patenting over US 6,703,420 is maintained for claims 1-3, 7, 9-10.

Please note that applicants have deleted the issued species from claims 4-5 but the issued scope wherein R1 and R2 do not contain heterocyclic substituents are still fully embraced by the instant claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dent et al. US 6,147,107 in view of Wermuth.

Determination of the scope and content of the prior art (MPEP §2141.01)

Dent et al. disclosed anticipatory compounds having the MEK1 inhibitory activity, see col. 16 claim 18.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the Dent et al. method of using SL327 is that the instantly claimed compounds incorporated bio-isosteres for the phenyl moiety. Wermuth

Art Unit: 1625

et al. taught that the replacement of a phenyl moiety with its conventional bio-isosteres (see p.206-213) is expected to obtain modified compounds with similar activity.

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

One having ordinary skill in the art would be motivated to modify the known compound of Dent with the conventional bio-isostere moieties because more compounds with similar activity in MEK1 can be obtained for testing/screen and the modified compounds are conventionally known to result in similar biological activity and utility. Bioisosterim is a rational approach to drug design.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

.OACS/Chang  
Jan 31, 2005

  
Celia Chang  
Primary Examiner  
Art Unit 1625